



# New technologies and innovations in breast surgery

## *Novas tecnologias e inovações em cirurgia mamária*

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### ■ ABSTRACT

**Introduction:** Breast surgery with silicone implants is gaining popularity and has become the most performed plastic surgery worldwide. However, there is increasing concern about the safety of silicone breast implants due to associated complications. **Objective:** To review existing technologies, technological trends, and existing methods to minimize complications related to silicone breast implants. **Methods:** We conducted a literature review of articles describing new technologies and trends to reduce complications related to silicone breast implants, along with information on patents and manufacturers of silicone breast implants. **Results:** We initially identified 78 articles, out of which 40 were shortlisted for publication. All articles had a common aim of obtaining better results and reducing complications related to silicone implants, either in aesthetic or reconstructive surgeries. **Conclusion:** The search for a breast implant that reduces possible and frequent complications, especially biofilm formation, infectious processes, and abnormal immune response, was the focus of most articles studied. Acellular dermal matrix and fat grafting have been reported in the literature as promising alternatives.

**Keywords:** Mammoplasty; Breast implants; Silicone elastomers; Reconstructive surgical procedures/trends.

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## ■ RESUMO

**Introdução:** A cirurgia de mama, especialmente as associadas aos implantes de silicone, teve uma crescente popularização, tornando-se a cirurgia plástica mais realizada no mundo. Junto com esta proliferação, observa-se um aumento da preocupação com a segurança dos implantes mamários de silicone, pelas intercorrências relacionadas. **Objetivo:** Revisar métodos existentes para minimizar as complicações relacionadas com implante mamário de silicone, bem como as tecnologias existentes e tendências tecnológicas para implantes mamários de silicone. **Métodos:** Foi realizada revisão de artigos científicos relacionados com novas tecnologias e tendências para redução das complicações relacionadas com implantes mamários de silicone, bem como as patentes e fabricantes de implante de silicone mamário. **Resultados:** Identificamos inicialmente 78 referências, sendo reduzido para 40 para publicação, todos com linhas de pesquisas que buscam melhores resultados e redução das complicações relacionadas com implantes de silicone, seja esta cirurgia com objetivo estético ou reconstrutivo. **Conclusão:** A busca por um implante mamário que reduza as possíveis e frequentes complicações, principalmente a formação do biofilme, processos infecciosos e resposta imune, é o foco da maioria das pesquisas encontradas. Com o mesmo objetivo, porém surgindo mais recentemente como alternativas, existem as pesquisas para o uso de matriz dérmica acelular e a lipoenxertia, com boas expectativas.

**Descritores:** Mamoplastia; Implantes de mama; Elastômeros de silicone; Procedimentos cirúrgicos reconstrutivos/tendências.

## INTRODUCTION

Thousands of women opt for breast surgery, since well-endowed breasts are an indicator of feminine beauty in various cultures and there is great social appeal and media stimulation advocating these procedures<sup>1</sup>; this has recently led to a revolution in the silicone industry, with a significant increase in the number of manufacturers offering various models, different profiles, gel densities, and various characteristics of envelopes for pleasant and safe results.

Breast surgery with silicone implants has off late been experiencing growing popularity as the most commonly performed aesthetic surgical procedure worldwide<sup>2</sup>. With aesthetic silicon breast implant surgeries being performed worldwide only in 2016, according to statistics from the International Society of Aesthetic Plastic Surgeons, Brazil was responsible for 13.64% (206,250) of these.

In fact, the number of breast reconstruction surgeries is growing, with silicone implants being used more predominantly than regional tissue flaps due to the ability of silicone to mimic natural breasts<sup>3</sup>.

Representatively, only in the United States, 300,000 new cases of breast cancer are diagnosed every year. Of these, 118,000 patients choose to undergo breast reconstruction, out of which 69% opt for silicone implants while the remaining 31% use flaps<sup>4</sup>.

Alongside the increasing popularity of silicone breast implants, there is an increased concern about their safety<sup>5</sup>, manufacturing defects<sup>6</sup>, and the most common complications related to the presence of synthetic material in the breast region, such as capsular contracture, infections, biofilm formation<sup>7</sup>, bleeding, rupture<sup>8</sup>, and rarer conditions such as siliconomas<sup>9</sup>, and more recently, breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)<sup>10-13</sup>, which have been reported in several articles<sup>1</sup>.

These complications may lead to unexpected additional treatments and reinterventions in 25 to 36% patients<sup>14</sup>. In another study<sup>1</sup>, rates of reoperation were compared between two brands of manufacturers 6 years after the procedure. Reintervention rates of 28% and 19.4% were observed in aesthetic surgeries performed with Allergan® implants and Mentor® implants, respectively. In the same study, reintervention rates of 51% and 33.9% were observed in repair

surgeries performed with Allergan® implants and Mentor® implants, respectively, with a significant increase in costs incurred during the treatment of these complications<sup>14</sup>, in addition to compromised patient-physician relationship and uncertainty about the safety and reliability of silicone implant surgeries.

On literature review, we identified research articles aiming at obtaining better results and especially, minimizing complications related to silicone implants, in both aesthetic and reconstructive surgeries.

## OBJECTIVE

This study aims to review the existing technologies and technological trends related to silicone breast implants and methods to minimize related complications.

## METHODS

We carried out a literature review of articles published in the last 10 years related to patents, manufacturers, and new technologies and trends to reduce complications related to silicone breast implants.

## RESULTS

Initially, 78 articles were found, out of which 40 were shortlisted for publication. All articles had a common aim of obtaining better results and reducing complications related to silicone implants, in both aesthetic or reconstructive surgeries.

The published studies, new implant models, and issued patents focus on research of factors that diminish the immune response, improve the coating surface, and nanotechnology, in addition to exploring the feasibility of implants with acellular dermal matrix and fat grafting. Research has also been carried out to find ways to improve the implant content.

Factors associated with complications of breast implants were studied and may be related to the implant itself, surgical management, manufacturing artifacts, and the response of the body to silicone<sup>8</sup>.

## DISCUSSION

For ease of understanding, we have divided the discussion into four topics:

1. Surface of silicone implants
2. Latest technology in silicone implants
3. Association of silicone implants with acellular dermal matrix
4. Association of silicone implants with fat grafting

## Surface of silicone implants

Most studies found in the literature were focused on the improvement of the surface of breast silicone implants.

It is important to understand that the surface properties of the implant impact the inflammatory cellular response, because the surface is the interface between the implant and organic tissues, and the primary site where the antigen-antibody reaction occurs. Development of implants is fundamental in providing satisfactory solutions to minimize long-term clinical complications<sup>15</sup>.

Therefore, there has been a lot of research for its improvement, especially to avoid infection and capsular contracture.

**Topical antibiotics.** The use of topical antibiotics has been mentioned in several studies, demonstrating that when instilled or implanted into the external surface of silicone implants, antimicrobials decrease the formation of biofilm, capsular contracture, seroma, and infection<sup>16</sup>.

Importantly, recent clinical studies<sup>17-19</sup> reported that infections due to breast silicone prostheses can be treated at a single time using both aesthetic and repair surgery, with subsequent resolution of the infection.

**Povidone-iodine solution.** At the end of 2017, the Food and Drug Administration (FDA) approved the use of Betadine (povidone-iodine) to prevent the formation of biofilm and infection, as it has a broad spectrum against Gram+ bacteria, which are related to capsular contracture, and Gram-, more related to BIA-ALCL. Previously, since 2000, the FDA believed that povidone-iodine could degrade the silicone implant capsule, and this change represents a major advance in the prevention of complications.<sup>20</sup>

Recently, a controlled experimental study has demonstrated decontamination of infected breast silicone implants after brushing povidone-iodine for 1 minute and removing excess saline solution<sup>21</sup>. This leads to a heightened expectation of the treatment of infection in one surgical stage, as described in other studies<sup>17-19</sup>.

**Surface texture.** It is generally known that capsular contracture is more frequent in implants with a smooth surface and less frequent in microtextured and macrotextured surfaces. Some recent studies<sup>22-24</sup> sought to minimize this complication but could not completely avoid it.

More recently<sup>23,24</sup>, there is evidence of increased bacterial contamination in silicone implants with macrotextured surfaces due to more space being available for bacterial growth.

Moreover, scientific evidence<sup>10-13</sup> shows that BIA-ALCL is more likely to occur in macrotextured silicone implants.

## Alternative surfaces of silicone breast implant

Novel surfaces aimed at preventing complications related to the textured surface of conventional implants are being developed.

A study reported the development, manufacture, and evaluation of an implant surface obtained from human tissue aimed at biomimicking, with increased compatibility and decreased capsular contracture<sup>25</sup>. This *in vitro* experimental study used a treated and prepared fat surface of 3 patients fixed with gold and palladium and demonstrated a decreased inflammatory response that was evaluated by cytokine and C-reactive protein levels.

Another study described a modification of the surface with implantation of carbon ions<sup>26</sup> tested in 3 different doses in order to increase biocompatibility. This implantation reduced surface roughness, bacterial adhesion, and capsule formation in an *in vitro* and *in vivo* experimental study in 16 rats. The results were more evident with higher doses of carbon ions.

A patent issued in 2017 (registration No. US2017/0049549 A1 by Bayat and contributors - University of Manchester, UK) describes a new biomimetic textured surface topography, with roughness control on macro, micro, and nanoscales simulating the topography (basement membrane and papillary dermis) of human skin. No experimental or clinical trials analyzed this patent.

Another patent (registration No. US0209618 A1 by Mark Anton, 2017) describes a second outer layer of polytetrafluoroethylene (PTFE) to decrease capsular contracture, acting as a reservoir. It utilizes PTFE, rifampicin, verapamil,  $\alpha$ -tocopherol (Vitamin E), and methylprednisolone to reduce the risk of infection and biofilm formation, thus forming a third layer with slow or late release, promoting cellular adhesion. It would be used to confer a more natural appearance, similar to natural skin and lighter, because PTFE has a lower density than silicone. It makes use of nanotechnology that repels water (hydrophobia) helping in biocompatibility, with less possibility of capsular contracture. We found no clinical trials analyzing this patent as well.

## Nanotechnology in breast silicone implants

Nano and surface microtopography aim at influencing cell polarization, alignment, migration, coupling, adhesion, proliferation, and morphological nature at the nano and micro levels, thus leading to cells reacting more naturally to surrounding structures<sup>27</sup>.

Recent studies suggest that the inflammatory response in these new models is lower, with better scattered and spindle-shaped fibroblasts and milder surface reactions by macrophages, thus indicating a more favorable foreign body reaction<sup>1,27</sup>.

In the technological line, some studies describe a breast silicone implant coated with halofuginone nanofibers<sup>28</sup>, inhibitors of collagen synthesis type I that interferes with the synthesis of transforming growth factor  $\beta$  (TGF- $\beta$ ) which, in an experimental study using the submuscular plane of 28 rats, showed no systemic reaction; a decrease in histiocytes, CD68 marker (type I collagen), TGF- $\beta$ , fibroblasts, type I and III collagens; and capsular thickening.

More recently, a clinical study<sup>29</sup> analyzed 5813 breast implants, with a maximum of 3 years of follow-up, using implants with nano and microtextures, built with uniform topography using three-dimensional silicone printing to create optimized biocompatible external surfaces. The manufacturing was described as particle-free and did not use extrusion of foreign material to create the surface geometry, thus allowing a surface of uniform and controlled thickness. Complications such as seroma, infection, hematoma, dehiscence, rupture, and malposition of the implant occurred in 0.36% of the implants with nanotexture surface and in 1.06% of the surface implants with microtexture surface. However, capsular contracture and the eventual incidence of BIA-ALCL could not be evaluated conclusively in a short time period.

## Latest technology silicone implants

We identified 4 silicone breast implants utilizing innovative and recent technology:

**Ideal Implant®.** It is a structured breast implant approved by the FDA and Health Canada in November 2014 which combines the benefits of saline and gel implants with intercommunicate lumens filled with saline solution, with frontal and posterior valves for filling. It was subjected to screening in 502 patients, 399 undergoing primary augmentation and 103 undergoing implant replacement and used in 35 different cities by 45 certified plastic surgeons with 6-year follow-up in 438 cases (87.3%). The satisfaction reported by the patients was 89.7% in primary cases and 91.6% in cases of implant replacement, and the satisfaction reported by surgeons was 92.6% in primary cases and 94% in cases of implant replacement. Contractures of Baker grades III and IV were observed in 5.7% of primary cases and 11.5% of cases of implant replacement. Rupture/deflation were observed in 1.8% of primary cases and 4.7% of cases of implant replacement.

**Microchip or Microtransponder.** Two articles<sup>18,29</sup> described a 9×2.1-mm sized radiofrequency microchip or microtransponder positioned inside the silicone gel near the center of its base, for identification and postoperative tracking by Radio-Frequency Identification (RFID), with a specific device of the

manufacturer Motiva®. RFID is a technological trend in other specialties such as veterinary. In the field of breast implants, it provides technical information about the implant. It is expected that in the future, RFID can store data from breast exams, hospital data from surgery, and global online updates.

The presence of RFID raised questions about its safety in imaging diagnostic methods, especially magnetic resonance imaging (MRI), with possible interference in the diagnosis of breast neoplasms, because it has a ferrite/copper antenna and iron is a material with great interference with artifacts on MRI. Initial evaluations show that RFID is compatible with clinical MRI, with a magnetic field of 1.5 or 3.0 Tesla, causing temperature increase (3 °C) after 15 minutes of continuous pulse (regular exams rarely exceed 3 minutes), and not showing any RFID displacement or torsion.

Initial evaluations show that an artifact is seen on MRI, being greater in the inner posterior face of the implant with extension to the chest wall, without significantly affecting the breast tissue and subcutaneous tissue. Further studies need to be conducted to evaluate this interference, especially if the RFID migrates to the interior of the implant over the years, and in cases of implant rotation with the base positioned next to the breast tissues.

**B-Lite®.** It refers to a light silicone breast implant which relies on the reduction of mechanical tension on the tissues to reduce pain in the postoperative period. It consists of silicone gel with borosilicate crystal microspheres, chemically attached to the silicone gel, fixed by a curing process and treated to increase the hydrophobic property and ensure that it remains fixed to the silicone gel without mixing and avoiding overflow of these microspheres, which leads to a reduction in the weight of the implant by up to 30%<sup>31</sup>. In this study, conducted in 100 cases, the B-Lite® implant was used in half of the patients and conventional Eurosilicone® and Allergan CUI® gel implants were used in the other half, with access through the breast crease and the subglandular plane in more than 90% of the cases. A statistically significant reduction in pain and shorter recovery time was demonstrated by the Fischer's test and Cox regression model<sup>32</sup>.

**Diagon/Gel 4Two® implant.** The Polytech® Diagon/Gel 4Two® implant consists of an implant with polyurethane coating (macrotecture) and two types of gel inside, a less dense posterior one and a higher density anterior one to better position the areola and support the residual breast tissue<sup>33</sup>.

A preliminary study with 894 cases followed for 5.5 years, showed low rates of complications with no statistical significance, with 2 cases of late seroma, 4

cases of hematomas, no case of capsular contracture, and having a patient satisfaction rate of 90%. Since it is a new type of implant, further statistically significant studies need to be conducted to better evaluate complications, if any.

### Association of silicone implants with acellular dermal matrix

More recently, acellular dermal matrix (ADM) has appeared as an alternative especially for breast reconstructive surgery with silicone implants to improve the positioning of the implants and tissue expansion dynamics, providing greater intraoperative filling and lower frequency of expansion sessions, leading to superior aesthetic results. The refinement of the technique and accumulated experience have decreased the morbidity initially related to ADM<sup>34</sup>.

It has now emerged as a potential tool for surgical prevention of capsular contracture. ADMs are immunologically inert, minimizing capsular formation in experimental models, which results in decreased inflammatory process, proliferation of myofibroblastic cells, and capsular thickness. This reduction is observed even in irradiated tissues.

Some surgeons modified ADMs by performing fenestrations to improve support, and the results were similar. It has already been used for both prevention and treatment of capsular contractures<sup>35</sup>.

Currently, there are several types of ADMs, and they have been used for breast reconstruction with the following silicone implants: AlloDerm (LifeCel Corp. Branchburg, NJ), DermaMatrix (Synthes Inc. West Chester, PA), FlexHD (Ethicon Inc. Somerville, NJ), Strattice (Lifecell Corp), and SurgiMend (TEI Biosciences Inc. Waltham Mass.). They differ in terms of the origin of the tissues, processing, storage, sterility, and need for surgical preparation.

A recent meta-analysis<sup>34</sup> compared results of several ADMs obtained from human cadavers and used in breast reconstruction. Seventeen retrospective articles and one randomized article were evaluated. The study evaluated complications (infection, seroma, flap necrosis, reconstruction failure, and general complications) in the Flex HD, Dermamatrix, and Alloderm ADMs. The authors concluded that complications were similar in the 3 ADMs evaluated. However, the results were poorly consolidated due to the scattered data from the various articles evaluated.

A study published in 2013<sup>36</sup> evaluated the costs of breast reconstruction with and without ADM and showed that the use of ADM significantly decreased postoperative follow-ups. However, the high cost of

ADMs did not exceed the cost obtained with a lower number of follow-ups.

The use of the fibrin silk mesh to coat the implant has been described as an alternative to coating with acellular tissue<sup>9</sup>. It is made with silk, associated with polyethylene oxide, and is manufactured with a technique using polymers and metal nanofibers.

### Association of silicone implant with fat grafting (lipofilling)

Autologous fat grafts have gained increasing attention and wide acceptance due to improved results in breast reconstruction. They have limitations on isolated use due to soft consistency. Thus, a combination of the classic silicone implant technique with simultaneous handling of subcutaneous tissue with fat grafting is the most versatile and powerful modality for obtaining synergistic results<sup>37</sup>.

Many clinical studies have shown a reduction in complications including capsular contracture<sup>38,39</sup> with the use of fat grafts. An experimental study conducted in 20 sows showed improvement in capsular contractures with autologous fat grafts, probably due to neovascularization of the tissues around the silicone implant<sup>40</sup>. Its use in cosmetic breast surgery is still controversial<sup>35</sup>.

## CONCLUSION

The search for a breast implant that reduces the common complications, especially the formation of biofilm, infectious processes, and immune response, is the focus of most of the studies found. Acellular dermal matrix and fat grafting have been reported in the literature as promising alternatives to that effect.

We conclude that there is a trend towards continuous improvement in breast augmentation surgery, with aesthetic or restorative purposes, with fewer complications and better results expected in the future.

## COLLABORATIONS

- RSG** Data curation, investigation, project administration, writing - original draft preparation.
- EBG** Supervision, writing - review & editing.
- HFCG** Supervision, writing - review & editing.
- LMF** Supervision, visualization.

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